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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,061	05/19/2000	STEPHAN R. TARGAN	P-PM 4097	1578

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EXAMINER

GABEL, GAILENE

ART UNIT PAPER NUMBER

1641

DATE MAILED: 05/08/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/575,061

Applicant(s)

TARGAN ET AL.

Examiner

Gailene R Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 2/8/02 in Paper No. 11 is acknowledged and has been entered. Claims 1-2 have been amended. Currently, claims 1-13 are pending. Claims 1-7 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2-7 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Specifically, it is unclear how the detection step is effected in the absence of a label.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

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by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Braun et al. (US 6,033,864) for reason of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braun et al. (US 6,033,864) in view of Targan et al. (US 5,932,429).

Response to Arguments

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5. Applicant's arguments filed 2/8/02 have been fully considered but they are not persuasive.

A) Applicant argues that the detection step can be performed with or without a label. Applicant specifically contends that detection of IgA anti-OmpC antibody can be performed directly through antibody labeling or indirectly through secondary antibody such as an enzyme-linked secondary antibody.

Applicant's argument is not persuasive because use of enzyme-linked secondary antibody for detection exemplifies detection using enzyme as label, i.e. enzyme label. Thus, it remains unclear how detection of the IgA anti-OmpC antibody can be performed without the presence of any type of label.

B) Applicant argues that Braun et al. only describe diagnosis of ulcerative colitis by detection of pANCA reactive porin antigen having linear or conformational homology to OmpF, OmpC, or another E.coli porin. Applicant argues that Braun et al. do not teach detecting IgA anti-OmpC antibodies to diagnose Crohn's disease. Applicant further argues that ulcerative colitis is a disorder distinct from Crohn's disease.

In response, Braun et al., indeed, describe detection of immunoglobulin (IgA) anti-OmpC antibodies from a sample of a patient suspected of having inflammatory bowel disease by contacting the sample with porin antigen under conditions suitable for a complex formation of the porin antigen with antibody to porin antigen, i.e. anti-porin antibody or immunoglobulin to porin, in the sample (column 11, lines 16-67). Braun et al. teach that the porin antigen has a linear and conformational homology to OmpC or

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another E. coli porin (column 12, lines 1-9) just as disclosed at page 9, lines 9-16 in Applicant's specification. Thus, the anti-porin antibody described supra which complexes with the porin antigen or OmpC antigen, is immunoglobulin or IgA anti-OmpC antibody such as recited in the rejected claims. Further in page 6, lines 36-41 of Braun et al., the patient suspected of having inflammatory bowel disease is one suspected of having ulcerative colitis (UC) and exhibiting symptoms of UC or Crohn's disease. Therefore, claims 1-4 are anticipated by Braun et al. in teaching that Crohn's disease in a subject can be diagnosed using OmpC antigen to complex with anti-OmpC immunoglobulins present in the sample obtained from the subject.

C) Applicant argues that Targan et al. do not cure the deficiencies of Braun et al. because Targan et al. do not describe diagnosis of Crohn's disease but only a subtype of the Crohn's disease. Further, Applicant argues that Targan et al. teach assaying the presence or absence of pANCA which is a neutrophil antigen and do not teach or suggest using OmpC to detect IgA anti-OmpC antibody for diagnosis of Crohn's disease.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Braun et al., indeed, describe detection of immunoglobulin (IgA) anti-OmpC antibodies from a sample of a patient suspected of having inflammatory

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bowel disease by contacting the sample with porin antigen under conditions suitable for a complex formation of the porin antigen with anti-porin antibody or immunoglobulin to porin, in the sample. Braun et al. teach that the porin antigen has a linear and conformational homology to OmpC or another E. coli porin. Thus, the anti-porin antibody described supra which complexes with the porin antigen or OmpC antigen, is immunoglobulin or IgA anti-OmpC antibody. Further, Braun et al. referred to the patient suspected of having inflammatory bowel disease as one suspected of having ulcerative colitis (UC) and exhibiting symptoms of UC or Crohn's disease. Therefore, Braun et al. disclose that Crohn's disease in a subject can be diagnosed using OmpC antigen to complex with anti-OmpC immunoglobulins present in the sample obtained from the subject. Targan et al. is incorporated with the teaching of Braun et al. for the disclosure that Crohn's disease and its subtypes can also be diagnosed by determining the presence of anti-Saccharomyces cerevisiae antibodies and pANCA in a patient's sample (see column 12, lines 63-67). Targan et al. further disclose that the antigen specific for ASCA which is prepared from yeast cell wall mannans or phosphopeptidomannans (PPM), i.e. ATCC strain #38926, is contacted with a patient's serum sample under conditions suitable for forming complexes with ASCA. The presence of complexes with ASCA is indicative of the presence of Crohn's disease or a subtype, thereof. Therefore, one of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate the teaching of Targan in using ASCA as markers for diagnosing Crohn's disease in addition of pANCA, into the method taught by Braun which uses OmpC porin antigen in detecting the presence of anti-

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OmpC antibodies as markers, to diagnose Crohn's disease, because cumulative use of various markers in a multivariate analysis to diagnose disease such as Crohn's disease, which manifests itself in patients as having symptoms that overlap with other inflammatory bowel diseases, would provide or allow for increased specificity and accuracy in diagnosis of such disease, just as shown by Targan in using both ASCA and pANCA as combined specific markers for diagnosis of Crohn's disease.

6. For reasons aforementioned, no claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703)

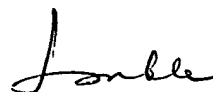
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305-0807. The examiner can normally be reached on Monday to Thursday, 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel
April 3, 2002



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

05/01/02